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10/099,818	03/14/2002	Iqbal Grewal	146392002400	2744

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EXAMINER	
GAMBEL, PHILLIP	
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1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/099,818	GREWAL, IQBAL	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14,15,19,32,33,36-52,55,58 and 59* is/are pending in the application.

4a) Of the above claim(s) *19,40-45,58 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 14-15, 32-33, 36-39, 46-52 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/02/2009, 10/08/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 10/02/2009, has been entered.

Applicant's amendment, filed 10/02/2009, has been entered.

Claim 1 has been amended.

Claims 56-57 have been canceled.
Claims 9-13, 16-18 and 20-31, 34-35 and 53-54 have been canceled previously.

Claims 1-8, 14-15, 19, 32-33, 36-52, 55, 58 and 59 are pending.

The following of record is reiterated for applicant's convenience.

Newly submitted claims 58-59 (like claims 40-45 previously submitted) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
Newly submitted claims 58-59 are drawn to methods of further administering a cytotoxic or chemotherapeutic agent previously not claimed.
The newly submitted claims encompass the administration of cytotoxic or chemotherapeutic agents that differ in structure and function from the combination of anti-CD40 antibodies / anti-CD20 antibodies previously elected in the claimed methods of treating a neoplastic disease or disorder.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Given these differences between the newly submitted cytotoxic and chemotherapeutic agents, the previous prosecution on methods employing CD40-specific antibodies and CD20-specific antibodies in the absence of cytotoxic and chemotherapeutic agents and the non-coextensive searches based upon such differences, newly submitted claims 58-59 have been withdrawn from consideration as being drawn to the non-elected species based upon original presentation.

Therefore, given the above, including issues under the various patent statutes and how they would apply to methods versus product claims; one or more of the following reasons apply, as indicated in the previous Office Action:
(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph

The newly submitted claims would be subject to election of species.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 19, 40-45 and 58-59 have been withdrawn from consideration as being directed to a non-elected invention or species. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03.

As pointed out previously, applicant's election of Group I and the species of a CD40-specific antibody and a CD20-specific antibody as well as multiple myeloma in the reply filed on 11/14/2005 has been acknowledged.

Also, consistent with the previous indication, claims 1-8, 14-15, 32-33, 36-39, 46-52 and 55 are under consideration in this application as they read on CD40-specific antibodies and CD20-specific antibodies as the specific agents as well as the various neoplastic diseases claimed in the interest of compact prosecution.

2. The text of those sections of Title 35 USC not included in this Office Action can be found in a prior Action.

This Office Action will be in response to applicant's amendment, filed 10/02/2009.

The rejections of record can be found in the previous Office Actions, mailed 08/08/2008 and 04/03/2009.

3. Upon reconsideration of the cancellation of claims 56-57, filed 10/02/2009; the previous rejection under 35 U.S.C. 112, first paragraph, written description has been withdrawn.

4. Given the addition of Strom et al. (in Therapeutic Immunology, edited by Austen et al., Blackwell Science, Cambridge MA, 1996; see pages 451-456) (1449; #6) to the obviousness rejection of record and

and Hollingsworth ("Seattle Genetics: SGN40 Still Alive After Lymphoma Bust", BioWorld Today-20(192): 1, 4, October 6, 2009) and Seattle Genetics News Release ("Seattle Genetics Announces Discontinuation of Dacetuzumab Phase Iib Diffuse Large B-Cell Lymphoma Clinical Trial", October 5, 2009) (1449; #1) to address applicant's arguments;

New Grounds of Rejection have been set forth herein.

Claims 1-8, 14-15, 32-33, 36-39, 46-52 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Siegall et al. (U.S. Patent No. 6,843,989) (892; of record) in view of Li et al. (U.S. Patent No. 6,495,129), Hanna et al. (US 2001/0018041 A1) and Grillo-Lopez (U.S. Patent No. 6,455,043) (892; of record), Benoit et al. (Immunopharmacology 35: 129-139, 1996) (1449; #59) essentially for the reasons of record and in further view of Strom et al. (in Therapeutic Immunology, edited by Austen et al., Blackwell Science, Cambridge MA, 1996; see pages 451-456) (1449; #6), Hollingsworth ("Seattle Genetics: SGN40 Still Alive After Lymphoma Bust", BioWorld Today-20(192): 1, 4, October 6, 2009) and Seattle Genetics News Release ("Seattle Genetics Announces Discontinuation of Dacetuzumab Phase lib Diffuse Large B-Cell Lymphoma Clinical Trial", October 5, 2009) 9 (1449; #1).

Applicant's arguments in conjunction with the 132 Lewis Declaration concerning the unpredictable and unexpected results of the combination of anti-CD40 antibodies and anti-CD20 in a SCID mouse model, have been fully considered but have not been found convincing essentially for the reasons of record and those presented herein.

In addition to the obviousness rejection of record,
Strom et al. (in Therapeutic Immunology, edited by Austen et al., Blackwell Science, Cambridge MA, 1996; see pages 451-456) teach that:
A multitiered approach to immunosuppressive therapy is applied similar in principle to that used in chemotherapy, in which several agents are used simultaneously, each of which is directed against a different molecular target. Additive-synergistic effects are achieved through application of each agent at a relative low dose, thereby limiting the toxicity of each individual agent while increasing the total immunosuppressive effect.
(see entire document, particularly page 451, column 1, paragraph 2).

As to the use of combination therapy targeting different molecular targets, such dosing of combination therapy is a result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing of combination therapy with agents that target different molecular targets resulting in additive-synergistic effects were known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Further, the Seattle Genetics News Release and the BioWorld Today article by Hollowingworth both indicate that the combination of the anti-CD40 SGN-40 antibody dacetuzumab and the anti-CD20 rituximab antibody did not meet their primary endpoint of a superior complete reponse rate in partiesn with B cell lymphoma (see entire document).

Therefore, applicant's arguments in conjunction with the Lewis 132 Declaration based upon the reliance of the SCID animal model is inconsistent with the clinical results and with applicant's arguments concerning the teachings of the prior art.

Also, given the teachings of therapeutic anti-CD40 antibodies and anti-CD20 antibodies and associated combinations in cancer therapeutic regimens including addressing different mechanisms of action to achieve the same therapeutic endpoints,
additive-synergistic effects with anti-CD40 antibodies, including the S2C6 antibody specificity, and anti-CD20 antibodies, including the rituximab antibody specificity, would have been expected to work at some level such as trough the application of each agent at a relative low dose, thereby limiting the toxicity of each individual agent or other therapeutic agents in the treatment of cancer, while increasing the total therapeutic effect at the time the invention was made.

Also, the prior art may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art.

In addressing applicant's arguments concerning different types of anti-CD40 antibodies,
the prior art would be consistent with employing different type of anti-CD40 antibodies, such as antagonist and agonist antibodies, antibodies that bind to different epitopes, unconjugated antibodies, and antibodies conjugated to a cytotoxic agent,
provided that such antibodies (e.g., anti-CD40 antibodies or anti-CD20 antibodies in this particularly case) targeted the appropriate markers (e.g., CD40, CD20) and inhibited the interactions and functions mediated via such markers or the cells expressing said markers in order to inhibit undesirable immune responses, including undesirable immune response such as those associated with neoplastic disorders encompassed by the claimed invention.

The following of record is maintained and is reiterated for applicant's convenience.

In response to applicant's arguments against the references individually (combination therapy with S2C6 anti-CD40 antibodies and anti-CD20 antibodies, in vitro assays, animal models), one cannot show non - obviousness by attacking references individually where the rejections are based on combinations of references. In re Keller , 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In response to applicant's arguments that there is no prima facie case of obviousness to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine 5 USPQ2d 1596 (Fed. Cir 1988) and In re Jones 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the prior art does teach treating neoplastic diseases with anti-CD40 antibodies and anti-CD20 antibodies, including their combination

While applicant focuses on the mechanism of action of the instant anti-CD40 S2C6 antibody and the anti-CD40 antibodies employed in the prior art,

the prior art does teach administering the instant anti-CD40 S2C6 antibody to treat neoplastic diseases and

the prior does teach the combination of anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases at the time the invention was made.

In addition to the teachings above, it was known and practiced at the time the invention was made that the use of cancer therapy relies upon a number of basic principles, including combination therapy wherein different agents are used and can be directed at a different molecular target.

While applicant focuses on the issues that known anti-CD40 antibodies at the time the invention was made acted via different mechanisms,

Applicant ignores that the prior art does teach administering the instant anti-CD40 S2C6 antibody to treat neoplastic diseases and

the prior does teach the combination of anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases at the time the invention was made.

In this case the teachings of the prior art indicated success in administering the instant anti-CD40 S2C6 antibody to treat neoplastic diseases and the prior does teach the combination of anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases at the time the invention was made in the face of having to solve a similar problem would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art.

The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) see MPEP 2144

With respect to applicant's reliance upon unexpected results based upon the Examples in the instant specification,

it is noted that applicant relies upon results based upon an certain parameters under certain experimental conditions of an experimental model of cancer, wherein such models may be / can be helpful in analysis, such models have been known not to be predictive of therapy in humans,

it is noted that these experimental models rely upon the administration of antibodies at or nearly at the time of inoculating tumor cells, which is not the normal course of cancer therapeutic regimens, which occur after cancer is diagnosed.

Further, it does not appear that the instant Examples differ from the prior art teachings of treating neoplastic diseases by targeting two different molecular targets of CD40 and CD20 at the time the invention was made.

Also, it is noted that it appears that the Experimental model compared anti-CD40 antibody or anti-CD20 antibody alone in comparison to the combination of anti-CD40 antibody and anti-CD20 antibody.

However, it appears that the Experimental model does not compare two doses of either anti-CD40 antibody or anti-CD20 antibody as a control of providing the same amount of therapeutic antibodies in comparison to the combination of anti-CD40 antibody and anti-CD20 antibody.

In the Experimental model, the combination of anti-CD40 antibody and anti-CD20 antibody resulted in animals receiving twice the amount of therapeutic antibody in comparison to receiving anti-CD40 antibody or anti-CD20 antibody.

Here, the asserted unexpected results do not appear unexpected nor commensurate in scope with the claimed invention.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g., anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (administering anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases) with no change in their respective functions and the combination would have yielded nothing more than predictable results of treating neoplastic diseases with the combination of anti-CD40 antibodies and anti-CD20 antibodies in the treatment of neoplastic diseases.

The rationale to support a conclusion that the claims would have been obvious is that a methods of anti-CD40 antibodies and/or anti-CD20 antibodies in the treatment of neoplastic diseases was made part of ordinary capabilities of one skilled in the art based upon the teachings of the prior art. One of ordinary skill in the art would have been capable of applying the known methods of treating neoplastic diseases by administering anti-CD40 antibodies and/or anti-CD20 antibodies would have been predictable to one of ordinary skill in the art at the time the invention was made.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (administering anti-CD40 antibodies and/or anti-CD20 antibodies in the treatment of neoplastic diseases) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying these known techniques, including known and practiced techniques of targeting different molecular targets with different agents in cancer therapeutic regimens that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

The rationale to support a conclusion that the claim would have been obvious is that a person of ordinary skill has good reason to pursue the known options (to administer anti-CD40 antibodies and/or anti-CD20 antibodies in the treatment of neoplastic diseases and combination therapy encompassing targeting different molecular targets with different agents) within his or her technical grasp. This leads to the anticipated success of treating neoplastic diseases anti-CD40 antibodies and anti-CD20 antibodies. It is likely the product not of innovation but of ordinary skill and common sense.

The following is reiterated for applicant's convenience.

Siegall teach methods of treating cancer, including leukemias, lymphomas (e.g. non-Hodgkins lymphoma), solid tumor and multiple myeloma (e.g. see Therapeutic Uses, including Table 1 on columns 22-23 and Claims) with CD40-specific antibodies, including the S2C6 CD40-specific antibody of the instant invention (see entire document, including Claims)

Siegall differs from the claimed methods by not disclosing the known use of combination therapy in the treatment of neoplastic diseases or disorders, including the use of anti-CD20 antibodies in the treatment of such neoplastic diseases or disorders.

Li et al. teach the well known use of combination therapy in the treatment of such neoplastic diseases or disorders (e.g., columns 86-),
including leukemias, lymphomas and multiple myeloma as the elected species (e.g., columns 102 and column 151),
including Rituximab / anti-CD20 antibodies (see column 147, paragraph 3)
and anti-CD40 antibodies, including agonistic antibodies (e.g., see column 3, paragraph 3)
Grillo-Lopez teach treating various tumors with CD20-specific antibodies, including Rituixmab (see columns 5-8 (see entire document) and teachings the expression of CD20 on multiple myeloma (e.g. see columns 15-16, overlapping paragraph) in addition to leukemias and lymphomas (e.g. see Field of the Invention on column 1 and Detailed Description of the Invention and Claims).

Benoit et al. provides additional motivation of combining anti-CD40 antibodies with anti-CD20 antibodies in the treatment of B cell lymphomas.
Benoit et al. teach the increased inhibition of proliferation of B cell lymphomas following litigation of CD40, and CD20, for example (see entire document, including Abstact and Discussion).

Given both the therapeutic use of CD40-specific antibodies and CD20-specific antibodies to treat various neoplastic diseases, including leukemias, lymphomas, myelomas and solid tumors, the ordinary artisan would have been motivated to combine the two antibody specificities in combination therapies to target other neoplastic tissues in order to increase the efficacy of cancer treatment. As taught by all of the prior art references, combination therapies, including combination with antibodies or combination of antibodies with more traditional chemotherapy and radiotherapy were well known and practiced by the ordinary artisan at the time the invention was made to increase efficacy of treatment and to minimize toxic effects of such treatment in order to meet the needs of the patients (e.g., see Detailed Descriptions of Siegall and Grillo-Lopez). The claimed recombinant antibodies and antigen-binding fragments were well known and employed at the time the invention was made. Modes of administration (e.g. simultaneously and sequentially) were practiced by the ordinary artisan as standard regimens in meeting the needs of the patient at the time the invention was made.

In this case the teachings of the prior art do provide for the use of anti-CD40 antibodies in the treatment of certain neoplastic disorders and diseases and do indicate success in treating neoplastic disorders and diseases with anti-CD40 antibodies in combination with anti-CD20 antibodies that would have led one of ordinary skill in the art at the time the invention was made to combine the references to solve a well known problem in the art. The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983). See MPEP 2144.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the combination of the prior art disclosure in motivating the ordinary artisan to administer anti-CD20 antibodies and anti-CD40 antibodies to treat patients with neoplastic diseases or conditions.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to treat patients with neoplastic diseases or conditions with anti-CD20 antibodies and anti-CD40 antibodies,
incorporating the combination of anti-CD20 antibodies and anti-CD40 antibodies
in therapeutic regimens with patients with neoplastic diseases or disorders would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such therapeutic methods to treat said neoplastic diseases and disorders.

Applicant's arguments have not been found persuasive.

5. Given the canceled claims in copending USSN 11/537,559,
the previous provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending USSN 11/537,559 has been withdrawn.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
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